

**Notice of Allowability**

Application No.

09/769,736

Applicant(s)

LE PAGE ET AL.

Examiner

Karen Cochran Carlson, Ph.D.

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to January 10, 2005.
2. ☒ The allowed claim(s) is/are 1,3,10,11, 17, and 24.
3. ☒ The drawings filed on 26 November 2001 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☒ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)           |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance  |
|   | 9. <input type="checkbox"/> Other _____   |

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This Office Action is in response to the After-Final response filed January 10, 2005. Claims 1-23 are currently pending. Claims 2, 4-9, 12-16, and 18-23 have been withdrawn from further consideration by the Examiner because these claims are drawn to non-elected inventions. Claims 1, 3, 10, 11, 17, and 24 are currently under examination.

An **extension of time** under 37 CFR 1.136(a) is required to place this application in condition for allowance. During a telephone conversation conducted on February 14, 2005, David Kelly (Reg. No. 53,106) requested an extension of time for **1 MONTH(S)** and authorized the Director to charge **Deposit Account No. 50-0206** the required fees for this extension.

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with David A. Kelly (Reg. No. 53,106) for Laurence H. Posorske (Reg. No. 34,698) on February 14, 2005.

**Examiner's Amendments to the Claims:**

Please cancel Claims 2, 4-9, 12-16, and 18-23.

1. (currently amended)) An isolated protein or polypeptide, said protein or polypeptide selected from the group consisting of:

a) [Group B] Group B Streptococcus protein or polypeptide comprising the amino acid sequence of SEQ ID NO: 72, [or] and

b) a protein or polypeptide that is a derivative or variant of SEQ ID NO: 72, said protein or polypeptide comprising a sequence having at least 50% identity to SEQ ID NO: 72, wherein said derivative or variant is able to protect against Group B *Streptococcus* challenge.

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3. (currently amended) [Derivatives or variants of the proteins or polypeptides of claim 1 which shows at least 70% identity to those proteins or polypeptides] The protein or polypeptide of claim 1, wherein said protein or polypeptide that is a derivative or variant of SEQ ID NO: 72 comprises a sequence having at least 70% identity to SEQ ID NO: 72.

10. (currently amended) An immunogenic composition comprising [one or more of the proteins or polypeptides] at least one protein or polypeptide of claim 1 [,or derivatives or variants of] or claim 3.

11. (currently amended) [An] The immunogenic composition[as claimed in] of claim 10, [which] wherein said composition is a vaccine.

17. (currently amended) A kit for the detection of [Group B] Group B Streptococcus comprising at least one [Group B] Group B Streptococcus protein or polypeptide of claim 1 or [derivative or variant of] claim 3.

**Examiner's Amendments to the Specification:**

Please replace the first paragraph on page 1 with:

— This application is a continuation of PCT/GB99/02444, filed July 27, 1999, which claims priority to provisional application 60/125,163, filed March 19, 1999, and GB 9816335.5, filed July 27, 1998. —

At page 14, please replace the first paragraph with:

—Fig 1: shows a number of full length nucleotide sequences encoding Group B *Streptococcus* proteins and the corresponding amino acid sequences. —

At page 14, at the third paragraph, replace "Fig 3" with — Fig 3(i)-(iii) —.

At page 15, replace "Fig 4" with — Figs 4a to 4e —.

At page 15, replace "Fig 5" with — Figs 5a to 5e —.

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The following is an **Examiner's Statement of Reasons for Allowance**: The prior art of record does not teach or suggest Group B *Streptococcus* protein or polypeptide comprising the amino acid sequence of SEQ ID NO: 72, or a derivative or variant of said protein or polypeptide comprising a sequence having at least 50% identity to SEQ ID NO: 72, wherein said derivative or variant is able to protect against Group B *Streptococcus* challenge. Therefore, the claims are allowable over the art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER